

Notice of Allowability

Application No.

10/667,077

Applicant(s)

KAJIYAMA ET AL.

Examiner

Humera N. Sheikh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 17 January 2006.
2. ☒ The allowed claim(s) is/are 1, 3-11 and 14-20.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

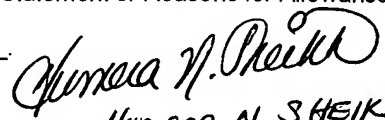
* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date 04/05/06.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


HUMERA N. SHEIKH
PATENT EXAMINER
TC-1600

DETAILED ACTION

Status of the Application

Receipt of the Response to Non-Final Office Action, the Amendment, Applicant's Arguments/Remarks and the Terminal Disclaimer, all filed 01/17/06 is acknowledged.

Claims 1, 3-11 and 14-20 are pending in this action. Claim 1 has been amended. Claims 2, 12 and 13 have previously been cancelled. Claims 1, 3-11 and 14-20 are allowed.

Terminal Disclaimer

The terminal disclaimer filed on 01/17/06 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of U.S. Patent No. 6,656,492 has been reviewed and is accepted. The terminal disclaimer has been recorded.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Joseph R. Snyder on 04/05/06.

The application has been amended as follows:

In the Claims:

In Claim 11, line 3, the symbol “~” has been replaced with the term “to”.

In the Abstract:

A new, concise Abstract has been provided.

Allowable Subject Matter

Claims 1, 3-11 and 14-20 are allowed.

The following is an examiner's statement of reasons for allowance:

The instant invention is drawn to a quick disintegrating tablet in buccal cavity, said quick disintegrating tablet comprising: (a) a plurality of drug-containing particles, wherein each particle comprises a bitter tasting drug and a pharmaceutical preparation carrier, wherein each particle has a mean diameter of approximately 50 to approximately 250 μm and an apparent specific gravity of approximately 0.5 to approximately 1.2, obtained by spray drying; and (b) a saccharide.

The primary reasons for allowance are that the prior art does not disclose nor fairly suggest or teach a tablet for buccal cavity that comprises a plurality of drug-containing particles, whereby each particle has a specific gravity of approximately 0.5 to approximately 1.2, and a mean diameter of approximately 50 to approximately 250 μm wherein the tablet is obtained by spray drying. The quick disintegrating tablets, which contain the drug-particles, are obtained by spray drying and have a specific gravity (~0.5 to ~1.2) and a specific mean diameter (~50 to

~250 μm), which is not disclosed or taught by the prior art. The specific mean diameters and specific gravity, as claimed, is considered a critical feature in Applicant's invention since these parameters (specific gravity/particle diameter) aid in the ability of masking or decreasing the bitter taste provided by the drug. The prior art fails to provide for the mixing of drug-containing particles with a specific mean particle diameter and specific mean gravity that are obtained by employing a spray drying method. The instant invention demonstrates an improvement over prior art formulations because it provides for a quick disintegrating tablet that is formulated such that the bitter taste of the drug is alleviated, thus offering excellent effects of palatability of the tablet. The instant quick disintegrating tablet also offers sufficient tablet strength whilst quickly disintegrating and dissolving in the mouth of the consumer. Thus, in view of the improvements demonstrated by the instant invention, and the lack of teachings by the prior art of the instant claim limitations, the instant invention is rendered patentable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604.

The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Patent Examiner

Art Unit 1615

April 05, 2006


TE-1600

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